Claims

1. Isopropanol/water mixed solvate of olanzapine which contains 2 molecules of water and 1 molecule of isopropanol per 2 molecules of olanzapine.

2. Isopropanol/water mixed solvate of olanzapine characterized by the x-ray structure shown in Figure 1.

3. Isopropanol/water mixed solvate of olanzapine characterized by a NMR spectrum in $CDCl_3$ showing peaks at approximately 1.20 ppm, 2.20-2.40 ppm and 4.03 ppm.

4. Isopropanol/water mixed solvate of olanzapine characterized by the NMR spectrum shown in Figure 2.

5. Process for the preparation of the isopropanol/water mixed solvate of olanzapine according to any one of claims 1 to 4, which comprises crystallizing it from a solvent mixture comprising isopropanol and water in a ratio of at least 9 to 1 parts by volume.

6. Process according to claim 5, wherein the solvent mixture comprises isopropanol and water in a ratio of at least 20 to 1 parts by volume.

7. Process according to claim 5 or 6, wherein the solvent mixture comprises isopropanol and water in a ratio of at least 35 to 1 parts by volume.

8. Process according to any one of claims 5 to 7, wherein the crystallization is effected by adding the water to a solution comprising olanzapine and the isopropanol.

9. Process for the preparation of form I olanzapine, wherein the isopropanol/water mixed solvate according to any one of claims 1 to 4 is used.

10. Process according to claim 9, wherein

(a) the isopropanol/water mixed solvate is converted to a methylene chloride solvate of olanzapine, and

(b) the methylene chloride solvate is converted to form I olanzapine.

11. Process according to claim 10, wherein in step (a) a solution of the isopropanol/water mixed solvate in methylene chloride is prepared, the solvent is partly evaporated and the remaining solution is cooled.

12. Process according to claim 10, wherein in step (a) a solution of the isopropanol/water mixed solvate in methylene chloride is prepared, a drying agent is added to the solution, the drying agent is removed from the mixture and the methylene chloride solvate of olanzapine is recovered.

13. Process according to claim 12, wherein anhydrous $CaSO_4$ is used as drying agent.

14. Process according to any one of claims 10 to 13, wherein the methylene chloride solvate is methylene chloride hemisolvate of olanzapine.

15. Process according to any one of claims 10 to 14, wherein in step (b) the methylene chloride solvate is suspended in isopropanol.

16. Process according to claim 15, wherein the ratio between methylene chloride solvate (kg) and isopropanol (l) is 1:5 to 1:2.

17. Process according to any one of claims 10 to 16, wherein in step (b)

methylene chloride hemisolvate is dried under vacuum at a temperature of 30 to 55°C for 6 to 36 hours,

the dried hemisolvate is suspended in isopropanol,

the suspension is stirred at a temperature of 15 to 35°C for 15 to 60 min, and

the form I olanzapine is separated.

18. Process according to claim 9, wherein the solid isopropanol/water mixed solvate of olanzapine is mixed with solid olanzapine of form I and the particle size of the mixture is reduced.

19. Process according to claim 18, wherein the mixture comprises up to 10% and in particular up to 5% by weight of form I olanzapine.

20. Process according to claim 18 or 19, wherein the mixture of reduced particle size is dried in a vacuum drier at temperatures ranging from room temperature to 80°C, preferably from room temperature to 60°C and most preferred from 40 to 50°C.

21. Process according to claim 20, wherein the dried material is suspended in isopropanol, the solid is separated by filtration and dried.

22. Process according to claim 21, wherein the dried material is suspended in isopropanol in a weight (kg) to volume (l) ratio of 1:5 to 1:2, in particular 1:3 to 1:2.

23. Process for the preparation of any other solvate or hydrate forms of olanzapine, or mixtures thereof, wherein the isopropanol/water mixed solvate of olanzapine according to any one of claims 1 to 4 is used.

24. Process for the preparation of anhydrous forms of olanzapine, wherein the isopropanol/water mixed solvate of olanzapine according to any one of claims 1 to 4 is used.

25. Use of the isopropanol/water mixed solvate of olanzapine according to any one of claims 1 to 4 for the preparation of any other solvate or hydrate forms of olanzapine, or mixtures thereof, or for the preparation of anhydrous forms of olanzapine.

26. Process for preparing form I olanzapine, wherein at least one of (a) a precursor for olanzapine form I and (b) olanzapine form I is crystallized or precipitated from a liquid medium which medium is present in a container wherein the surfaces of the container contacting the medium are comprising at least one polymer.

27. Process according to claim 26, wherein a precursor for olanzapine from I is crystallized or precipitated.

28. Process according to claim 27, wherein the precursor is methylene chloride hemisolvate of olanzapine.

29. Process according to any one of claims 26 to 28, wherein the precursor or the olanzapine form I has been prepared

using the isopropanol/water mixed solvate according to any one of claims 1 to 4.

30. Process according to any one of claims 26 to 29, wherein the surfaces of the container contacting the medium are consisting of at least one polymer.

31. Process according to any one of claims 26 to 30, wherein the polymer contains fluorine.

32. Process according to any one of claims 26 to 31, wherein the polymer is selected from polytetrafluoroethylene, fluorinated ethylen propylene copolymer, perfluor alkoxy polymer, or ethylene tetrafluoroethylene copolymer.